

December 14, 2015

VIA Courier and U.S. Mail

National Freedom of Information Officer
U.S. Environmental Protection Agency
FOIA and Privacy Branch (2822T)
1301 Constitution Avenue, NW
Room 6416 West
Washington, DC 20004
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Donald C. McLean

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Re: Request for Information Pursuant to the Freedom of Information Act

Dear Sir or Madam:

On behalf of our client, Dow AgroSciences LLC (“DAS”), we submit this request pursuant to the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, *et seq.* This request seeks any and all raw data underlying federally funded epidemiologic research studies, which studies the Environmental Protection Agency (“EPA”) received, reviewed, and/or relied upon in formulating a proposed rule revoking all tolerances for the pesticide chlorpyrifos. *See Chlorpyrifos; Tolerance Revocations*, 80 Fed. Reg. 69080-01 (Nov. 6, 2015). Specifically, we request any and all raw data underlying any of the following:

1. The Mothers and Newborn Study of North Manhattan and South Bronx, conducted by the Columbia Children’s Center for Environmental Health at Columbia University, including, but not limited to, any published journal articles reporting the results of the study (the “Columbia Study”);
2. The Mt. Sinai Inner-City Toxicants, Child Growth and Development Study, conducted by the Mt. Sinai Center for Children’s Environmental Health and Disease Prevention Research, including, but not limited to, any published journal articles reporting the results of the study (the “Mt. Sinai Study”); and
3. The Center for Health Assessment of Mothers and Children of Salinas Valley Study, conducted by researchers at the University of California, Berkeley, including, but not limited to, any published journal articles reporting the results of the study (the “CHAMACOS Study”).¹

For each of the studies listed above, this request seeks the documents or other sources of information (*e.g.*, electronic files) containing one or more of the data elements set forth in the attached Appendix B. Please provide us with copies of the documents or the electronic files containing the raw data.

¹ A non-exhaustive list of relevant publications reporting results of the three enumerated studies is set forth in the attached Appendix A.

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In response to a previous FOIA request and subsequent FOIA appeal (HQ-FOIA-01618-12; HQ-APP-2012-003392) seeking raw data underlying the Columbia Study (specifically, raw data underlying multiple published journal articles summarizing the results of the Columbia Study), EPA advised that it was not in possession of any of the raw data underlying the Columbia Study, nor had EPA used the Columbia Study “in developing an agency action that has the force and effect of law,” *i.e.*, “EPA has not *proposed or finalized* any action under FIFRA or the [FFDCA].” (emphasis added). Thus, EPA took the position that the data were not subject to disclosure by EPA under OMB Revised Circular A-110.

We understand based on statements by EPA representatives at an October 21, 2015 Pesticide Program Dialogue Committee meeting that EPA is now in possession of raw data underlying at least one of the above-referenced studies. In addition, EPA has issued a proposed rule revoking all tolerances for chlorpyrifos stating, in part, that the above-referenced studies “have raised some uncertainty about EPA’s historical risk assessment approach for chlorpyrifos with regard to the potential for neurodevelopmental effects that may arise from prenatal exposure to chlorpyrifos.” 80 Fed. Reg. 69080, 69087. Thus, EPA is now relying on the studies to “develop[] an agency action that has the force and effect of law” and must, pursuant to OMB Revised Circular A-110, request and make the data underlying these studies publicly available under FOIA.

Moreover, EPA is currently accepting public comments on its proposed revocation rule until January 5, 2016, which comments EPA will consider in issuing a final regulation determining whether revocation of some or all tolerances for chlorpyrifos is appropriate. EPA’s proposed rule states that any issues not raised in comments on the proposed rule will be deemed “waived” and may not be raised in objections to the final rule. Thus, without access to the raw data underlying the studies now or in the very near future, DAS and other interested parties may effectively be foreclosed from providing meaningful comment on several aspects of the reliability of the studies, as well as EPA’s reliance on the studies to inform its decision-making related to chlorpyrifos tolerances. We respectfully submit that this would be contrary to the letter and spirit of OMB Revised Circular A-110, would contravene EPA and Administration policies concerning data access and transparency in scientific decision-making, and would violate DAS’s due process rights.

Accordingly, for these reasons, we respectfully request that EPA release any raw data in the Agency’s possession supporting any of the above-referenced studies immediately. In addition, we request that, pursuant to OMB Revised Circular A-110, EPA request from the studies’ investigators and release under FOIA any additional data underlying the above-referenced studies not currently in the Agency’s possession. Given the time-sensitive nature of the request, we respectfully request that EPA expedite processing of this request.

This request does not apply to any documents or portions thereof contained in these files that are Confidential Business Information. In addition, this FOIA request does not seek test data, manufacturing processes, or the confidential statement of formula for any pesticide product. Finally, this request does not seek any personnel, medical, or similar files subject to protection under FOIA Exemption 6, 5 U.S.C. § 552(b)(6) (2000). As noted in our prior FOIA appeal, we are willing to accept the requested raw data with personal identifying information redacted or deleted, as necessary to protect the privacy interest of study participants.

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We would be pleased to pay reasonable costs related to duplicating and shipping the requested information. Please contact me should it appear that the costs will exceed \$100.

If we may be of assistance with this matter, please do not hesitate to contact me at (202) 857-6469. Thank you in advance for your assistance.

Sincerely,

A handwritten signature in blue ink that reads "Donald C. McLean". The signature is written in a cursive, flowing style.

Donald C. McLean, Esq.

APPENDIX A: PUBLICATIONS

- Berkowitz, G., Wetmur, J. G., Birman-Deych, E., Obel, J., Lapinski, R. H., Godbold, J., Holzman, I. R., and Wolff, M. 2004. "In Utero Pesticide Exposure, Maternal Paraoxonase Activity, and Head Circumference," *Environ Health Persp* (112:3), pp 388-391.
- Berkowitz, G. S., Obel, J., Deych, E., Lapinski, R., Godbold, J., Liu, Z., Landrigan, P. J., and Wolff, M. S. 2003. "Exposure to indoor pesticides during pregnancy in a multiethnic, urban cohort," *Environ Health Perspect* (111:1) Jan, pp 79-84.
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- Bouchard, M. F., Chevrier, J., Harley, K. G., Kogut, K., Vedar, M., Calderon, N., Trujillo, C., Johnson, C., Bradman, A., Barr, D. B., and Eskenazi, B. 2011. "Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year Old Children," *Environ Health Perspect* (119) Apr 21, pp 1189-1195.
- Eaton, D. L., Daroff, R. B., Autrup, H., Bridges, J., Buffler, P., Costa, L. G., Coyle, J., McKhann, G., Mobley, W. C., Nadel, L., Neubert, D., Schulte-Hermann, R., and Spencer, P. S. 2008. "Review of the toxicology of chlorpyrifos with an emphasis on human exposure and neurodevelopment," *Crit Rev Toxicol* (38 Suppl 2), pp 1-125.
- Engel, S. M., Berkowitz, G. S., Barr, D. B., Teitelbaum, S. L., Siskind, J., Meisel, S. J., Wetmur, J. G., and Wolff, M. S. 2007. "Prenatal organophosphate metabolite and organochlorine levels and performance on the Brazelton Neonatal Behavioral Assessment Scale in a multiethnic pregnancy cohort," *Am J Epidemiol* (165:12) Jun 15, pp 1397-1404.
- Engel, S. M., Bradman, A., Wolff, M. S., Rauh, V. A., Harley, K. G., Yang, J. H., Hoepner, L. A., Barr, D. B., Yoltan, K., Vedar, M. G., Xu, Y., Hornung, R. W., Wetmur, J. G., Chen, J., Holland, N. T., Perera, F. P., Whyatt, R. M., Lanphear, B. P., and Eskenazi, B. 2015. "Prenatal Organophosphorus Pesticide Exposure and Child Neurodevelopment at 24 Months: An Analysis of Four Birth Cohorts," *Environ Health Perspect* Sep 29.
- Engel, S. M., Wetmur, J., Chen, J., Zhu, C., Barr, D. B., Canfield, R. L., and Wolff, M. S. 2011. "Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood," *Environ Health Perspect* (119:8) Aug, pp 1182-1188.
- Eskenazi, B., Harley, K., Bradman, A., Weltzien, E., Jewell, N. P., Barr, D. B., Furlong, C. E., and Holland, N. T. 2004. "Association of in utero organophosphate pesticide exposure and fetal growth and length of gestation in an agricultural population," *Environ Health Perspect* (112:10) Jul, pp 1116-1124.
- Eskenazi, B., Kogut, K., Huen, K., Harley, K. G., Bouchard, M., Bradman, A., Boyd-Barr, D., Johnson, C., and Holland, N. 2014. "Organophosphate pesticide exposure, PON1, and neurodevelopment in school-age children from the CHAMACOS study," *Environ Res* (134) Oct, pp 149-157.
- Eskenazi, B., Marks, A. R., Bradman, A., Harley, K., Barr, D. B., Johnson, C., Morga, N., and Jewell, N. P. 2007. "Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children," *Environ Health Perspect* (115:5) May, pp 792-798.
- Factor-Litvak, P., Insel, B., Calafat, A. M., Liu, X., Perera, F., Rauh, V. A., and Whyatt, R. M. 2014. "Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years," *PLoS One* (9:12), p e114003.
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- environment characteristics as determinants of early childhood neurodevelopment," *Am J Public Health* (101:1) Jan, pp 63-70.
- Marks, A. R., Harley, K., Bradman, A., Kogut, K., Barr, D. B., Johnson, C., Calderon, N., and Eskenazi, B. 2010. "Organophosphate pesticide exposure and attention in young Mexican-American children: the CHAMACOS study," *Environ Health Perspect* (118:12) Dec, pp 1768-1774.
- Perera, F. P., Rauh, V., Tsai, W. Y., Kinney, P., Camann, D., Barr, D., Bernert, T., Garfinkel, R., Tu, Y. H., Diaz, D., Dietrich, J., and Whyatt, R. M. 2003. "Effects of transplacental exposure to environmental pollutants on birth outcomes in a multiethnic population," *Environ Health Perspect* (111:2) Feb, pp 201-205.
- Rauh, V. A., Garfinkel, R., Perera, F. P., Andrews, H. F., Hoepner, L., Barr, D. B., Whitehead, R., Tang, D., and Whyatt, R. W. 2006. "Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children," *Pediatrics* (118:6) Dec, pp e1845-1859.
- Rauh, V. A., Perera, F. P., Horton, M. K., Whyatt, R. M., Bansal, R., Hao, X., Liu, J., Barr, D. B., Slotkin, T. A., and Peterson, B. S. 2012. "Brain anomalies in children exposed prenatally to a common organophosphate pesticide," *Proc Natl Acad Sci U S A* (109:20) May 15, pp 7871-7876.
- Whyatt, R. M., Camann, D., Perera, F. P., Rauh, V. A., Tang, D., Kinney, P. L., Garfinkel, R., Andrews, H., Hoepner, L., and Barr, D. B. 2005. "Biomarkers in assessing residential insecticide exposures during pregnancy and effects on fetal growth," *Toxicol Appl Pharmacol* (206:2) Aug 7, pp 246-254.
- Whyatt, R. M., Garfinkel, R., Hoepner, L. A., Andrews, H., Holmes, D., Williams, M. K., Reyes, A., Diaz, D., Perera, F. P., Camann, D. E., and Barr, D. B. 2009. "A biomarker validation study of prenatal chlorpyrifos exposure within an inner-city cohort during pregnancy," *Environ Health Perspect* (117:4) Apr, pp 559-567.
- Whyatt, R. M., Rauh, V., Barr, D. B., Camann, D. E., Andrews, H. F., Garfinkel, R., Hoepner, L. A., Diaz, D., Dietrich, J., Reyes, A., Tang, D., Kinney, P. L., and Perera, F. P. 2004. "Prenatal insecticide exposures and birth weight and length among an urban minority cohort," *Environ Health Perspect* (112:10) Jul, pp 1125-1132.
- Wolff, M. S., Engel, S., Berkowitz, G., Teitelbaum, S., Siskind, J., Barr, D. B., and Wetmur, J. 2007. "Prenatal pesticide and PCB exposures and birth outcomes," *Pediatr Res* (61:2) Feb, pp 243-250.
- Young, J. G., Eskenazi, B., Gladstone, E. A., Bradman, A., Pedersen, L., Johnson, C., Barr, D. B., Furlong, C. E., and Holland, N. T. 2005. "Association between in utero organophosphate pesticide exposure and abnormal reflexes in neonates," *Neurotoxicology* (26:2) Mar, pp 199-209.

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APPENDIX B: DATA ELEMENTS REQUESTED

INFANT CHARACTERISTICS

Birth weight (g)
 Head circumference (cm)
 Birth length (cm)
 Birth year
 Gestational age of newborn (wks)
 Newborn gender/infant sex
 Infant malformations
 Apgar scores
 Sex
 PON1 genotype

MATERNAL CHARACTERISTICS

Alcohol use during pregnancy
 Breastfeeding
 Cesarean delivery (0 = no; 1 = yes)
 Community (Harlem, WH, S Bronx, etc.)
 Complications of preg and delivery
 Country of birth
 Depressive symptoms (CES-D) @ 12 mo
 Ethnicity (0 = Dominican; 1 = African American)
 ETS in the home (0 = no; 1 = yes)
 HOME score (at testing)
 Household income, annual
 Illicit drug use during pregnancy
 Language spoken in home
 Marital status
 Maternal age (yrs)
 Maternal education
 Maternal hardship
 Maternal height
 Maternal IQ
 Maternal pre-pregnancy weight
 Maternal smoking during preg
 Maternal weight gain during pregnancy (lbs)
 Medications/drugs used during preg
 Parity (0 = nulliparous, 1 = at least one prior live birth)
 Poverty level
 PON1 genotype
 Race/ethnicity (White, AA, Hispanic, Other)
 Residential pesticide use
 Season of delivery (summer, winter, spring, fall)
 Smoking history, during pregnancy

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EXPOSURE FACTOR	Medium	Source
Cholinesterase at delivery	blood	Mother
Cholinesterase during pregnancy	blood	Mother
Cholinesterase	cord blood	Child
Butyrylcholinesterase	cord blood	Child
Butyrylcholinesterase at delivery	blood	Mother
Butyrylcholinesterase during pregnancy	blood	Mother
Chlorpyrifos at delivery	blood	Mother
Chlorpyrifos at delivery	cord blood	child
TCPy, prenatal sample 1	urine	Mother
TCPy, prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	Mother
Chlorpyrifos, week 32-34	air	Indoor
Chlorpyrifos, week 34-36	air	Indoor
Chlorpyrifos, week 36-38	air	Indoor
Chlorpyrifos, week 38-40	air	Indoor
Chlorpyrifos, postpartum	Meconium	Mother
DAP, DEP DAP, prenatal sample 1	urine	Mother
DAP, DEP DAP, prenatal sample 2	urine	Mother
, prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	Mother
Delivery date/time		Mother Admission date/time
Dates/time of all collection (in context of delivery)		

CHILD HEALTH ENDPOINTS

BNBAS assessment	<= 3 days; within 5 days; <= 2 months
Baley Scales of Infant Development	6, 12 ,24, 36 months
WISC-IV intelligence test	7 years
WPPSI-III	6 years
CBCL	24 months, 3.5 years
K-CPT	5 years
ADHD	3, 3.5, 5 years
Hillside Behavioral rating scale	
NEPSY	3.5 years
PDD	3, 3.5, 5 years